## REMARKS

In **Paragraph 1**, the Examiner requests that Serial No. 09/591,887 be replaced with the patent number of the now-issued patent. In reply, the amendment of paragraph 0001 offered above is intended to do exactly as requested and text claiming priority to U.S. Letters Patent No. 6,646,556 has been added. In view of this, it is believed that the instant objection has been made moot and should be withdrawn.

In **Paragraph 2**, the Examiner requests various typographical corrections to the specification. In is believed that the amendments offered *supra* have responded to every such request and, in view of this fact, it is further believed that the instant objections have been made moot and should be withdrawn.

## CLAIM OBJECTIONS AND REJECTIONS

### Objections Concerning the Claims

In **Paragraph 3**, it is said that Claims **12** and **20** are objected to under 37 CFR 1.75(c) which states that "(c)laims in dependent form shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim." It is further said that the preamble of Claims **12** and **20** refer to an "electronic patient monitor" and it is said to be unclear whether "electronic patient monitor" means the same thing as "apparatus in this context.

In reply, applicants have amended Claims **12** and **20** to replace the phrase "electronic patient monitor" with the more general term "apparatus". Thus, the instant objection has been made moot and should be withdrawn.

In **Paragraph 4**, the Examiner objects to the claims on various grounds and requires that certain informalities should be corrected. The amendments offered *supra* – and discussed previously in the "Amendments to the Claims" section – have modified the claims pursuant to the Examiner's suggestions. As a consequence, it is believed that the objections lodged in within this paragraph have been made moot and should be withdrawn.

### Claim Rejections under 35 USC 112

**Paragraph 5** contains a recitation of 35 USC 112. No response by the applicants is believed to be necessary.

In **Paragraph 6** it is said that Claims **21-28** are rejected under 35 USC 112, first paragraph, as failing to comply with the enablement requirement. It is said that Claim **21** recites

among other elements an "optically transmissive central core". The only disclosed embodiment having such a "core" is said to be that of Fig. **12F** (having core **1240**). It is further said that Claim **21** further recites an "upper" and "lower" external member having certain structural limitations (lines 3-6) which are said not to be described anywhere in the specification (although they are said to be depicted in cross-section in Fig. **12f**). Further, it is said that Claim **21** calls for a light "source" and "sensor" to be positioned "respectively at first and second ends" (emphasis in original) of the central core. However, Fig. **12F** is said to be described as having light sources **1242** "(w)ithin or proximate to the core **1240**" but it is said that light sensors (not shown in Fig. **12F**) are used at both ends of the core **1240** while light sources **1242** are at neither end. Dependent Claims **22-28** provide further recitations which also are said to lack support in the specification (at least with respect to the embodiment of Fig. **12F**). Thus, it is said that the specification and drawings fail to provide enablement for what is presently recited in Claims **21-28**.

In response, please note as a preliminary matter that Claim **21** has been amended to improve its readability by changing several instances of "sensor" to the phrase "patient sensor" in order to more clearly differentiate it from the term "light sensor" that also appears in this claim. This was done even though it was believed that the intent of the original claim language as-filed was clear and in spite of the fact that such change was not required by the Examiner.

Turning now to the instant rejection, the Examiner states that the "upper" and "lower" external members that are referred to in Claim **21** are not described anywhere in the specification. In reply, applicants would note that in the patient monitoring context the use of such members to protect delicate circuitry that is used in a patient's bed is well known to those of ordinary skill in the art. That is, sensors of the sort discussed here are conventionally enclosed in a plastic or

plastic-like waterproof sheath (e.g., paragraph 0061 of the instant specification) to protect the working components from exposure to the moisture that is often encountered in a patient's bed. (See, e.g., Figures **7** through **9** where this idea is illustrated for pressure-sensitive mats). In many conventional mat-type patient sensor embodiments, the protective sheath is formed by sealing together (with heat or glue) two identically sized rectangular plastic-like (e.g., polyester) sheets along their peripheries, thereby creating a roughly rectangular interior region that is protected at least partially against invasion by moisture. A brief discussion of such external members may be found in paragraphs 0061 and 0062 of the instant specification in connection with a discussion of pressure sensitive mats and further discussed at greater length within the various patents and applications incorporated by reference in this case. A preferred embodiment of the "upper" and "lower" members of Figure **12F** will be a waterproof sheath of the sort discussed previously.

Of course, the applicants are not required to describe in detail such well known aspects of a patient monitoring art. As the U.S. Supreme Court has said:

> If a mechanical engineer invents an improvement on any of the appendages of a steam-engine. . . he is not obliged, in order to make himself understood, to describe the engine, nor the particular appendage to which the improvement refers, nor its mode of connection with the principal machine. These are already familiar to others skilled in that kind of machinery. **He may begin at the point where his invention begins, and describe what he has made that is new, and what it replaces of the old.** That which is common and well known is as if it were written out in the patent and delineated in the drawings.

*Webster Loom Co. v. Higgins*, 105 U.S. (15 Otto.) 580, 582–86 (1882) (emphasis added). The instant inventor's improvement is in the field of patient position sensors, and not patient sensor covers. As such, the instant specification need only discuss the contribution of the instant inventors to the field (in this case an "optical core" for use in the prevention of decubitus ulcers)

and need not discuss the specifics of the protective coverings that are commonly used with in-bed patient sensors.

Further, the general mat-type sensor configuration that is preferred for use in connection with the instant application is common and well known to those skilled in the art and, thus, need not be specifically disclosed in the specification or drawings. Consider the more recent case, *In re Howarth*, 210 USPQ 689, 692 (C.C.P.A. 1981):

> It is well settled that the disclosure of an application embraces not only what is expressly set forth in words or drawings, but what would be understood by persons skilled in the art. As was said in *Webster Loom Co. v. Higgins et al.*, . . . the applicant "may begin at the point where his invention begins, and describe what he has made that is new and what it replaces of the old. **That which is common and well known is as if it were written out in the patent and delineated in the drawings.**"

(emphasis added).

Of course, the real issue is whether the disclosure presented herein is sufficient to enable one skilled in the art to practice the invention or, in the words of the Federal Circuit,

> The question is whether the disclosure is sufficient to enable those skilled in the art to practice the claimed invention, hence the specification need not disclose what is well known in the art.

*Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 221 USPQ 481, 489 (Fed. Cir. 1984). Since the goal of the instant application is to teach how to construct a patient sensor for detecting movement within a bed – and not how to construct a well known type of sensor for use therewith — in the opinion of the applicant Claim **1** as-filed does not need for support the appearance of a well-known sensor as a specific element of any drawing.

The Examiner further indicates that Claim **21** requires an "optically transmissive central core" and the single embodiment having such a core is said to be illustrated in Figure **12F**. In reply, applicant would agree that Figure **12F** is one such an embodiment. However, that is not

the only figure that is pertinent to this embodiment. For examples, Figures **12A** through **12E** illustrate optically transmissive "cores" only (without the enclosing external members) that would be suitable for use with the instant embodiment. Thus, applicants would take exception to a broad statement that only Figure **12F** is pertinent to or contains embodiments that utilize an "optically transmissive central core."

Next, the Examiner questions whether any disclosed embodiment of the instant invention includes a light source and a light sensor positioned respectively at first and second ends of the central core. As an initial matter it should be noted that this is not what the claim limitation requires. That is, all that is required in Claim **21** is that each end be in optical communication with a light source or a light receiver. Note further that nothing in this claim requires that the light source be *outside* of the central core, although that sort of embodiment would clearly be possible and within the scope of the claim as-intended. Indeed, and as the Examiner notes in other contexts, the specification clearly calls for a light source "[w]ithin or proximate to the core **1240**" (specification at paragraph **0073**).

Now, given this understanding of the clear language of Claim **21**, the applicants would point out by way of reply that Figure **12F** contains exactly such an embodiment, i.e., an embodiment where a light source is at one end of the central core and a light receiver / senor is located at the other end. Consider, for example, the light that is generated by the left most light source (i.e., "said first end of the central core is positionable to be in optical communication with a light source", **21(c)(c2)**) as measured by the optical sensor that is indicated to be at the opposite (i.e., right) end of the optical core (i.e., "said second end of the central core is positionable to be in optical communication with a light sensor", **21(c)(c2)**). In the instant example and for

purposes of illustration only, the emitted light **1246** of Figure **12F** would be sourced by the single hypothesized light source indicated and its light energy might either travel directly from the source to the light sensor or travel indirectly to it after reflection from the first end (e.g., in an arrangement similar to that illustrated in Figure **12A**). In this example, there is clearly a light source and sensor that are positioned at opposite ends of the central core as required by the Examiner.

Additionally, and further in response to the Examiner's question, note that Figure **12D** shows a light source external to the optical core and a light receiver **1230** at the remote (i.e., right most) end thereof. Thus, this figure provides still another example of an embodiment with a light source proximate to one end of the central core and a light receiver proximate to the other end.

Finally, Figures **12D** and **12E** taken together – and further in view of the language in the specification – clearly illustrate the use of a light source external to one end of the central core (Figure **12D**) and a light receiver at the opposite end of the central core and external thereto (i.e., for purposes of sensing the escaping light **1246**). As such, these two figures when properly combined in view of the specification provide still another example of an embodiment with a light source and a light receiver positioned respectively at first and second ends of the central core.

As such, it is believed that the instant rejection has been overcome and Claim **21** is in condition for allowance.

The Examiner further indicates that "[d]ependent claims **22-28** provide further recitations which also lack support in the specification (at least with respect to the embodiment of Fig. **12F**).

With respect to Claim **22**, applicants would note that selection of an external shape for the claimed apparatus is a design choice that is well within the capability of those of ordinary skill in the art. That being said, it should further be noted that Figures **1**, **2**, **7**, and **10** all contain embodiments of the instant invention that are generally rectangular in shape.

As such, it is believed that the rejection of Claim **22** is improper and should be withdrawn.

It is said that the limitations required by Claims **23** and **24** lack support in the specification.

With respect to Claim **23** and in reply, applicants would point to the specification at paragraph **0073** wherein it is clearly stated that the central core **1240** might be "light conductive plastic, an optical wave guide, etc." Further in paragraph **0069** it is clearly stated that: "The device **1210** might be, for example, a film, a sheet, or tubing of an internally-clear material such as plastic that is elastically deformable and which is at least partially reflective to light at its end **1255**."

As a consequence, it is believed that the rejection of Claim **23** is improper and should be withdrawn.

With respect to Claim **24**, it should be noted that whether the light conductive plastic takes the form of a sheet or a strand of fiber optic cable is a design choice well within the ability of one of ordinary skill in the art. Of course, the use of fiber optic cable is well known in the optics industry and is mentioned specifically (in another context) within the instant application within paragraph **0096**: "It should also be noted that the term "nurse call" as that term has been

used herein should be interpreted to mean, not only traditional wire-based nurse call units, but also any system for notifying a remote caregiver of the state of a patient, whether that system is wire-based (e.g., fiber optics, LAN) or wireless (e.g., R.F., ultrasonic, IR link, etc.)."

As such, it is believed that the language of Claim **24** ("at least one strand of fiber optic cable") is fully satisfied in the specification and/or the knowledge of one of ordinary skill in the art. As such, the instant rejection should be withdrawn.

It is said that the limitation of Claim **25** that requires that the upper and lower members be "impermeable to fluid" lacks support in the specification.

In reply, applicants would note that sensors that are intended for use within a patient's bed must be resistant to moisture (see, e.g., UL 1069 nurse call standard), whether that moisture might take the form of spills, urine, sweat, etc. Further, it is noted in paragraph **0060** that the outer members of pressure sensitive mats (generally) are often made from plastic: "As is illustrated in Figures **7** and **8**, a typical pressure sensitive mat contains an inner non-conductive layer **710** which is "sandwiched" between two outer flexible non-conductive layers **730** and **740** which are conventionally made of some sort of thin plastic-like material."

Of course, plastic (and plastic-like materials) are generally impermeable to moisture and, as such, a specific embodiment of the limitation that is required in Claim **25** may be found within the instant application.

Finally, it should be noted that the applicants have invented an optical sensor for use in determining the location of a patient on a support surface. As such, and as has been made clear by the Supreme Court in *Webster Looms* case cited *supra*, applicants need only explain what is "new" with respect to their invention and need not explain that which is "old" and well known.

In the instant case, design considerations involving the general composition, shape, etc. of in-bed (or in-chair) patient sensors are well known and thus need not be described herein.

As such, it is believed that the rejection of Claim **25** is improper and should be withdrawn.

It is said that the limitation of Claim **26** is not supported in the specification.

In reply, applicants would direct the Examiner's attention to Figure **12A** which clearly utilizes a light source at one end of the central core, a light receiver at the same end of the central core, and wherein "at least a portion of the light reaching said second end of said central core is reflected back toward said first end of said central core."

As such, it is believed that the language of Claim **26** is fully supported in the specification and figures and, as such, the instant rejection of this claim should be withdrawn.

It is said that Claim **27** contains limitations not fully supported in the specification.

In reply, applicant would draw the Examiner's attention once again to paragraph **0069** in which it is clearly stated that: "The device **1210** might be, for example, a film, a sheet, or tubing of an internally-clear material such as plastic that is elastically deformable and which is at least partially reflective to light at its end **1255**."

As such, the requirement of Claim **27** that the transmissive central core be comprised of "a sheet of optically conductive material" is fully supported in the specification and, as such, the instant rejection is improper and should be withdrawn.

It is said that Claim **28** contains limitations not fully supported in the specification.

In reply, applicants would indicate that Figures **12A-12C** disclose precisely such an embodiment. That is, Claim **28** requires an optically transmissive central core wherein the amount of light that is received by the receiver is a function of whether or not the patient is present on the support surface. Note that Figure **12A** illustrates a preferred embodiment when no patient is present thereon. Further, Figures **12B** and **12C** illustrate the same embodiment when the patient is present. Clearly, and as is described in the instant specification in paragraph **0069**, the amount of light that is sensed in when the patient is present (Figures **12B** and **12C**) will be different than the amount of light that is sensed in Figure **12A**.

As a consequence, it is believed that limitations of Claim **28** are fully supported in the instant specification and, as such, the instant rejection should be withdrawn.

In **Paragraph 7** the language of 35 USC 112 is presented. No reply by applicants is believed to be necessary.

In **Paragraph 8**, it is said that Claim **7** is rejected under 35 USC 112 as being indefinite as depending on itself.

In reply, applicants would note that Claim **7** has been amended to depend from Claim **6**.

As such, it is believed that Claim **7** as-amended is in condition for allowance, and the instant rejection should be withdrawn.

**Claim Rejections under 35 USC 102**

In **Paragraph 9** the language of 35 USC 102 is presented. No reply is believed to be necessary on the part of the applicants.

In **Paragraph 10**, it is said that Claims **1-2, 4-6, 8, 12, 15-16**, and **18-20** stands as rejected under 35 USC 102(e) as being anticipated by Menkedick et al. (US 6,320,510). It is said, among others, that "Menkedick et al implicitly defines "significant" patient movement by detecting when the patient moves "on the bed" from one location to another as determined by output from sensor 104.

In reply and turning first to Claim **1**, applicants would note that the Federal Circuit, in speaking on rejections under Section 102, has made it abundantly clear that :

> Anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, **arranged as in the claim.**

*Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 221 USPQ 481, 485 (Fed. Cir. 1984) (emphasis added).

In applicants' view, Menkedick is not a proper § 102 reference because it fails to disclose every element of Claim **1** of the instant application. In more particular, and reserving the right to contest additional aspects of Menkedick's disclosure in the future, it should be noted that nowhere in Menkedick is the concept of monitoring a patient for "significant movement" disclosed or suggested. That is, consider for example the following passage from paragraph **0089** of the instant applicant which provides a clear description of what is meant by the "significant movement" requirement of Claim **1**:

> If a change in position is detected before the end of the patient turn interval, the instant invention will continue to further monitor the patient to see whether he or

> she returns to the original position within the persistence time period (i.e., before the previously compressed tissue has time to reoxygenate, e.g., ten minutes or some other interval selected by a caregiver. If, as has been explained previously, the patient returns to his / her original position prior to the expiration of the reoxygenation period, the instant monitor will determine that this was not a significant movement and, as a consequence, the monitor will preferably sound an alarm at the end of the patient turn interval if the patient does not move again.

(Emphasis added). Thus, if the patient rolls to a new position and then quickly returns to the original position, such movement will not allow the previously-compressed tissues sufficient time to reoxygenate and, as such, the patient will be still be at risk of developing pressure sores. Menkedick never recognizes this aspect of the applicants' invention. Applicants could find no evidence that Menkedick captures the idea of a patient monitor / monitoring method that requires a patient to change location periodically and to *maintain* that changed for a predetermined period of time in order to avoid setting off an alarm. Menkedick merely reflects the known technology in the field of monitoring patients for pressure sores, i.e., a patient is monitored for movement of *any* kind and, after that movement is sensed, a timer is reset. However, the instant invention goes further. The instant invention continues to check the patient *after* he or she has moved and, if the patient returns to the original position the movement timer is *not* reset.

Thus, it is believed that Claim **1** of the instant invention is clearly distinguishable from Menkedick and that the instant rejection under § 102 should be withdrawn. Further, it is believed that on this same basis the rejection of any claims dependent from Claim **1** is similarly improper and should be withdrawn.

Similarly with respect to Claims **2, 4-6, 8,** and **12**, rejection under Section 102 is inappropriate because, depending as they do from Claim **1**, there is similarly no teaching or

suggestion in Menkedick of the concept of "significant movement" as utilized by the applicant and required in Claim **1(c)(c1** and **c2)**.

As a consequence, it is believed that rejection of Claims **1, 2, 4-6, 8,** and **12** under § 102 is inappropriate and should be withdrawn.

Turning next to Claims **15-16**, and **18-20** which currently stand as rejected under § 102, for all of the reasons set out previously it is believed that such rejection is inappropriate and should be withdrawn.

By way of explanation, turning first to independent Claim **15**, elements (c1) and (c2) clearly require that the monitor circuit at least be able to determine "a time since the patient last significantly changed location". As has been discussed previously, Menkedick does not teach or suggest the advantage of such an approach and further does not even recognize what is to be gained by monitoring a patient to determine – not just whether or not that patient has moved – but rather whether or not the patient has quickly returned to a previous position, thereby making the previous move unproductive. Menkedick's inventive approach will reset the alarm timer after any sort of move, even a move where the patient immediately returns to the previous position. This is, of course, not what applicants have invented.

As a consequence, it is believed that the instant rejection of Claim **15** under Section 102 is inappropriate and should be withdrawn.

With respect to Claim **16**, this claim currently stands as rejected under § 102 in view of Menkedick. In response, applicants would once again point out that Menkedick does not teach or suggest applicants' requirement of "significant movement."

As such and for all of the reasons discussed previously, rejection of Claim **16** under § 102 is believed to be inappropriate and its withdrawal is requested.

With respect to Claims **18-20**, these claims currently stand as rejected under § 102 based on Menkedick.

In response, for all of the reasons set out previously it is believed that these claims should be allowed. In more particular, each of these claims requires that the apparatus be capable of sensing a "significant movement" as that term has been previously defined herein. Of course, Menkedick does not recognize the advantage of such a feature. Since each of these claims is dependent from an independent claim that is believed to be allowable, such claims are allowable and, as such, rejection under § 102 is not appropriate.

Thus, it is believed that each of these claims is in condition for allowance and the instant rejection should be withdrawn.

In **Paragraph 11**, it is noted that Claims **3, 7, 9-11, 17**, and **29-30** would be allowable if rewritten to overcome the rejections under 35 USC 112 and/or objections under 37 CFR 1.75(a) and to include all of the limitations of the base claim and any intervening claims.

In reply, it is noted that Claims **3, 7, 9-11, 17**, and **29-30** have been amended herein to overcome each and every rejection under 35 USC 112 and/or objection under 37 CFR 1.75(a).

As such, it is believed that each of these claims as-amended is in condition for allowance and should be passed to issue.

Also in Paragraph 11 it is noted that Claims **13-14, 21-28,** and **32-33** would be allowable if rewritten to overcome the rejections under 35 USC 112 and/or objections under 37 CFR 1.75(a) set for in the office action.

In reply, applicants would indicate that these claims have been amended pursuant to the Examiner's suggestions and, as such, are believed to be in condition for allowance.

Finally, allowance of Claims **31** and **34-35** in Paragraph 11 in is acknowledged.

In **Paragraph 12** various items of prior art that are deemed to be relevant are made of record in the instant case. No reply by applicant is believed to be required.

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In view of the foregoing, it is submitted that all of the claims as-amended herein are in condition for allowance. Early and favorable action is, therefore, earnestly solicited.

Respectfully submitted,

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